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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,261	01/16/2004	Gerhard Moersdorf	06478.1497	5706

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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
GILBERT, ANDREW M	
ART UNIT	PAPER NUMBER
3767	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/758,261	MOERSDORF ET AL.	
	Examiner	Art Unit	
	Andrew M. Gilbert	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *24-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 January 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/5/05; 1/16/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I: Claims 1-23 in the reply filed on 1/22/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 24-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1/22/2007.

3. Thus, claims 1-23 are pending for examination.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on 5/5/2005 and 1/16/2004 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Specification

5. The Applicant is required to reference the priority to the German Patent 10301884.0 in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a). Also, see MPEP § 201.11.

Drawings

6. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the duckbill valve and luer-lock closure and screw thread must be shown or the feature(s) canceled from the

claim(s). The Examiner is not distinctly clear how a duck-bill valve or a luer-lock closure and screw thread would be incorporated into the nose section of the output connection piece shown in Fig 4. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-4, 7-10, 13, 19-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Brinon (5879336). Brinon discloses a sterile sheath (13; Fig 4) comprising: a sealable casing (13) made of plastic, the casing including an output connection piece (13), wherein the output connection piece includes a valve (2, Fig 1-3) whose direction of flow is exclusively from an injection syringe to the exterior, wherein an interior (Fig 1-8) of the sterile sheath is configured to receive the injection syringe, and wherein the output connection piece is configured to be connected to the syringe (Fig 3, 11, 10); wherein an outer region (12a) of the output connection piece is configured to receive a medical device, and wherein the medical device is one of a needle, an adapter, a multiport valve, and an infusion bottle (col 2, lns 50-52); wherein the sealable casing is at least partially transparent (col 3, lns 24-28);wherein the valve is one of a non-return valve (2); wherein the output connection piece includes a cone-shaped recess (10, 9; Fig 3) configured to receive a syringe cone of the injection syringe; wherein the output connection piece includes a hollow body (13) configured to receive a cylindrical section of the injection syringe; wherein the hollow body has a cylindrical shape (13; Fig 1-8); wherein the output connection piece includes, on an end opposite from the valve, an annular plate (22); the sealable casing further comprising a pressure pocket (20) configured to connect to the output connection piece; further comprising a sealing element (Fig 1, 6-8) to seal between the output connection piece and the pressure pocket; wherein the output connection piece includes a section configured as a cone (inner annular projection inside luer lock 12a – Figs 1, 3) to receive a cone-shaped recess of the medical device; wherein the output connection

piece and the medical device are connected by means of a swivel closure (12a); wherein the swivel closure is one of a luer-lock closure and a screw thread (12a).

9. Claims 1, 2, 4-7, 13, 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Kulle (4346704). Kulle discloses a sterile sheath (Fig 1-2) comprising: a sealable casing (34) made of plastic, the casing including an output connection piece (34), wherein the output connection piece includes a valve (40) whose direction of flow is exclusively from an injection syringe to the exterior, wherein an interior (47) of the sterile sheath is configured to receive the injection syringe, and wherein the output connection piece is configured to be connected to the syringe (Fig 1, 2, 47, 50); wherein an outer region (36, 28, 16, Fig 2) of the output connection piece is configured to receive a medical device, and wherein the medical device is one of a needle, an adapter, a multiport valve, and an infusion bottle (Fig 1-3); wherein the valve is one of a non-return valve (40); wherein the output connection piece includes at least one radial discharge aperture (48) sealable by means of an elastic ring element (40);wherein the elastic ring element is a tubular ring element (40; Fig 2), which encloses a portion of the output connection piece; wherein the output connection piece includes a cone-shaped recess (47) configured to receive a syringe cone of the injection syringe; the sealable casing further comprising a pressure pocket (14) configured to connect to the output connection piece; further comprising a sealing element (14, 36) to seal between the output connection piece and the pressure pocket; wherein the output connection piece

includes a section configured as a cone (34, 36, 38 receives 14, 28) to receive a cone-shaped recess of the medical device.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brinon. Brinon discloses the invention substantially as claimed except for expressly disclose the annular plate having an oval aperture. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have the annular plate have an oval aperture because the Applicant has not disclosed that having an annular plate with an oval aperture provides an advantage, is used for a particular purpose, or solves a stated problem. Furthermore, one of ordinary skill in the art would have expected the Applicants invention to perform equally well with the annular plate having a circular aperture of Brinon because the annular plate performs substantially the same function in substantially the same manner. Therefore, it would have been an obvious matter of design choice to modify Brinon to obtain the invention as specified in claim 11.

12. Claim 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brinon or Kulle. Brinon or Kulle discloses the invention substantially as claimed except for

expressly disclosing the output connection piece is formed by injection molding. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the output connection piece as taught by Brinon or Kulle with an output piece made by injection molding since it was well known in the art that injection molding is used to provide rigid plastic parts for medical devices.

13. Claims 14-16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brinon or Kulle. Brinon or Kulle discloses the invention substantially as claimed except for expressly disclosing wherein the pressure pocket is formed by injection molding, by a dipping method, or by means of extrusion-blow molding. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have the pressure pocket formed by injection molding, by a dipping method, or by means of extrusion-blow molding because the Applicant has not disclosed that having the pressure pocket formed by injection molding, by a dipping method, or by means of extrusion-blow molding provides an advantage, is used for a particular purpose, or solves a stated problem. Furthermore, one of ordinary skill in the art would have expected the Applicants invention to perform equally well with the pressure pockets of Brinon or Kulle because the pressure pockets perform substantially the same function in substantially the same manner. Furthermore, claims 14-16 are directed to a product by process and it has been held that the patentability of the product does not depend on its method of production (see MPEP 2112.02). Therefore, it would have been an obvious matter of design choice to modify Brinon or Kulle to obtain the invention as specified in claims 14-16.

14. Claim 17-18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brinon in view of Riuli (4713060). Brinon additionally discloses wherein the shoulder piece includes a snap-in lug (22) configured to engage a snap-in lug (20) on an annular plate of the output connection piece. However, Brinon does not expressly disclose wherein the pressure pocket includes a shoulder film-like plastic hood. Riuli teaches that it is known to have wherein the pressure pocket includes a shoulder film-like plastic hood(40) for the purpose of providing a flexible cover flexible enough to allow movement of the plunger while acting as a barrier for helping to blow the transfer of fluid and particulate matter between the chamber and the environment (Abstract). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pressure pocket as taught by Brinon with the film-like plastic as taught by Riuli for the purpose of providing a flexible cover flexible enough to allow movement of the plunger while acting as a barrier for helping to blow the transfer of fluid and particulate matter between the chamber and the environment (Abstract).

15. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brinon in view of Riuli in further view of Kulle. Brinon and Riuli disclose the invention substantially as claimed except for wherein the output connection piece further includes at least one radial discharge aperture sealable by means of an elastic ring element. Kulle teaches that it is known to have at least one radial discharge aperture (48) sealable by means of an elastic ring element (40) for the purpose of providing uni-directional flow with a low residual valve size (see Disclosure of Invention). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the one-way

valve as taught by Brinon and Riuli with the radial aperature and elastic ring vavle as taught by Kulle for the purpose of providing uni-directional flow with a low residual valve size (see Disclosure of Invention).

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. 3601151, 1563627, 2743724.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Andrew Gilbert

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER